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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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09/762,692

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Sabaratnam Sabanathan

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MINTZ, LEVIN, COHN, FERRIS, GLOVSKY AND POPEO, P.C

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EXAMINER

SHOME, ARUNDIPTA

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 09/762,692	Applicant(s) SABANATHAN ET AL.	
	Examiner ARUNDIPTA SHOME	Art Unit 3771	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 27-49 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 27-49 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 09 February 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. ____. |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>4-24-2006, 11-20--2006, 03-09-2007.</u> | 6) <input type="checkbox"/> Other: ____. |

DETAILED ACTION

1. Claims 27-49 are pending in this application.

Specification

2. The disclosure is objected to because of the following informalities: The specification is not organized in the standard format. Appropriate correction is required.

The following guidelines illustrate the preferred layout for the specification of a utility application. These guidelines are suggested for the applicant's use.

Arrangement of the Specification

As provided in 37 CFR 1.77(b), the specification of a utility application should include the following sections in order. Each of the lettered items should appear in upper case, without underlining or bold type, as a section heading. If no text follows the section heading, the phrase "Not Applicable" should follow the section heading:

- (a) TITLE OF THE INVENTION.
- (b) CROSS-REFERENCE TO RELATED APPLICATIONS.
- (c) STATEMENT REGARDING FEDERALLY SPONSORED RESEARCH OR DEVELOPMENT.
- (d) THE NAMES OF THE PARTIES TO A JOINT RESEARCH AGREEMENT.
- (e) INCORPORATION-BY-REFERENCE OF MATERIAL SUBMITTED ON A COMPACT DISC.
- (f) BACKGROUND OF THE INVENTION.
 - (1) Field of the Invention.
 - (2) Description of Related Art including information disclosed under 37 CFR 1.97 and 1.98.
- (g) BRIEF SUMMARY OF THE INVENTION.
- (h) BRIEF DESCRIPTION OF THE SEVERAL VIEWS OF THE DRAWING(S).
- (i) DETAILED DESCRIPTION OF THE INVENTION.
- (j) CLAIM OR CLAIMS (commencing on a separate sheet).
- (k) ABSTRACT OF THE DISCLOSURE (commencing on a separate sheet).
- (l) SEQUENCE LISTING (See MPEP § 2424 and 37 CFR 1.821-1.825. A "Sequence Listing" is required on paper if the application discloses a nucleotide or amino acid sequence as defined in 37 CFR 1.821(a) and if the required "Sequence Listing" is not submitted as an electronic document on compact disc).

Claim Rejections - 35 USC § 102

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3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claims 27- 32, 34, 36, 37, 40, 42, 43, 45, 47, and 49 are rejected under 35 U.S.C. 102(b) as being anticipated by Palmaz (US Patent 5,382,261).

Regarding Claim 27, Palmaz discloses a method and apparatus for treating individuals by occluding vessels (col. 1, lines 11-25). Palmaz discloses providing a blocking element 70, inserting the blocking element in a lung passageway of the individual (occluding pulmonary arteriovenous fistulae, col. 1 line 19). The blocking element prohibits air from flowing past the blocking element in inhalation and exhalation directions because the device seals off the inner wall surface of a vessel (col. 3 lines 1-3) and fluid is prevented from flowing past the blocking element 70. Palmaz also discloses releasing the blocking element in the passageway (col. 6, lines 5-25)

Regarding Claims 28 and 31, the blocking element expands from a compressed state and expands into engagement with the wall of the lung passageway (col. 2, lines 65-67 and col. 3 lines 1-5).

Regarding Claim 29, the blocking element forms an a sealing engagement with an air tight seal since fluid is prevented from flowing pas the blocking element 70 after engagement with the wall of the lung passageway (col. 3 lines 1-3).

Regarding Claim 30, a securing element 60 has a tubular shape (col. 2, line 57) which is suitable for engaging a wall of the lung passageway.

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Regarding Claims 32 and 43, the blocking element is cylindrical, as shown in Figure 2. The blocking element is also a plug, since a plug can be defined as a piece used to fill a hole, which is essentially what the blocking element is.

Regarding Claims 34 and 45, the securing element 60 is a stent.

Regarding Claims 36 and 47, the blocking element is a diaphragm since a diaphragm can be defined as a thin partition in a tube.

Regarding Claim 37, Palmaz discloses inserting a delivery tube into the lung passageway loaded with the blocking element (col. 2 lines 65-67), Palmaz also discloses guiding the delivery tube to a suitable location within the lung passageway prior to releasing it (col. 6 lines 27-35).

Regarding Claim 40, Palmaz discloses that the device can be used for a variety of conditions, one of which is closure of pulmonary arteriovenous fistulae, which is a lung disease.

Regarding Claim 42, Palmaz discloses an apparatus for blocking air flow through a lung passageway into a portion of a human or animal lung (abstract lines 1-5). A securing element 60 engages the wall of a lung passageway (col. 2 line 65 -col. 3 line 1). A blocking element 70 is attached to the securing element, so that the blocking element prevents air from flowing past the apparatus in inhalation and exhalation directions, since the apparatus forms a sealing bond with the vessel it occludes.

Regarding Claim 49, Palmaz discloses a method and apparatus for treating individuals by occluding vessels (col. 1, lines 11-25). Palmaz discloses providing a blocking element 70, inserting the blocking element in a lung passageway of the individual (occluding pulmonary arteriovenous fistulae, col. 1 line 19). The blocking element prohibits air from flowing past the blocking element in inhalation and exhalation directions because the device seals off the inner

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wall surface of a vessel (col. 3 lines 1-3) and fluid is prevented from flowing past the blocking element 70. Palmaz also discloses releasing the blocking element in the passageway (col. 6, lines 5-25).

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. Claim 33 is rejected under 35 U.S.C. 103(a) as being unpatentable over Palmaz in view of Carlisle et al (US Patent 5,658,330).

Regarding Claim 33, Palmaz does not disclose using resiliently deformable closed cell foamed plastics material for the plug, but discloses that plug 70 is made of silicone. Carlisle et al teaches using deformable closed cell silicone foam as a biocompatible material in a medical device implant. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to substitute silicone closed cell foam for the silicone plug of Palmaz since both materials were well known in the art at the time the invention was made, and substitution of one material for another would yield comparable performance.

7. Claim 35 is rejected under 35 U.S.C. 103(a) as being unpatentable over Palmaz in view of McNamara et al. (US Patent 5,147,370)

Regarding Claim 35, Palmaz does not disclose using a memory metal as the material for the securing element. McNamara et al. teaches a nitinol stent for hollow body conduits.

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Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to use nitinol as taught by McNamara as the material for the securing element of Palmaz since nitinol devices can be formed into a first predetermined shape above a transition temperature range, and below the transition temperature range the device will be highly ductile and can be plastically deformed into a second desired shape. This allows a user to insert a collapsed stent and apply heat to it to force the stent to expand into a desired shape, which makes delivery of the stent easier (McNamara col. 1 lines 60-68, col. 2 lines 1-5).

8. Claim 38 is rejected under 35 U.S.C. 103(a) as being unpatentable over Palmaz in view of McIntyre (US Patent 5,833,707).

Regarding Claim 38, Palmaz does not disclose that the blocking element is released by pushing the blocking element out of the delivery tube. McIntyre teaches stent deployment system that has a catheter, a sheath, and a push rod for delivering a stent. The stent is pushed out of the sheath with the push rod to deliver it (col. 10, lines 10-20). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to substitute the delivery system of Palmaz with the delivery system as taught by McIntyre to deliver the blocking element of Palmaz so that the stent of Palmaz can be delivered in a collapsed state inside the catheter to the desired body location and simply pushed out with the push rod and allowed to expand, which is a simple and reliable delivery system (McIntyre col. 3, lines 45-55).

9. Claim 39 is rejected under 35 U.S.C. 103(a) as being unpatentable over Palmaz in view of Sharma (Pulmonary Arteriovenous Fistulae, emedicine.com)

Regarding Claim 39, Palmaz disclose that the disclosed method and apparatus can be used for pulmonary arteriovenous fistulae (col. 1, line 19). Palmaz does not disclose providing a

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second blocking element and inserting it into a lung passageway. Sharma teaches that it was well known in that art (circa 1988) that a significant percentage of such fistulae are complex, having 2 or more feeding arteries or draining veins. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to provide a second blocking element to close a complex fistula in order to close all feeding arteries and/or veins of a complex fistula since Sharma teaches that such fistulae are common and all feeding arteries and/or veins must be treated.

10. Claim 41 is rejected under 35 U.S.C. 103(a) as being unpatentable over Palmaz in view of Auerbach et al (Localized pulmonary interstitial emphysema: treatment by bronchial occlusion. American Journal of Perintology, 1983 Oct. 1(1): 52-7)

Regarding Claim 41, Palmaz does not disclose using the occluding device to treat emphysema. Auerbach et al. teaches treating localized pulmonary interstitial emphysema by occluding the left mainstem bronchus. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to use the device of Palmaz to treat emphysema by using this device to occlude the left mainstem bronchus rather than the device used by Auerbach et al., because the device of Palmaz is easier to leave in place for longer periods of time - the device of Palmaz provides permanent occlusion of vessels (abstract lines 1-5) while balloon catheters are typically used temporarily.

11. Claim 48 is rejected under 35 U.S.C. 103(a) as being unpatentable over Palmaz.

Regarding Claim 48, Palmaz discloses that the blocking element 70 has a length of 10 mm (col. 5, line 28) and a first compressed diameter of 3.3mm (col. 5, line 24) expandable to a second larger diameter D" that is variable (col. 5, lines 40-45). Palmaz does not disclose that the

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second expanded diameter is between 5 and 11mm, but it would have been obvious to one of ordinary skill in the art at the time the invention was made to set the second expanded diameter to be in the range of 5-11mm in order to occlude a vessel with a diameter in that range.

Additionally, it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. In re Aller 105 USPQ 233.

Conclusion

12. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Thompson et al. (US Patent 5,919,224) discloses a device for occluding fluid flow in a lumen.

Huebsch et al. (US Patent 5,853,422) discloses an apparatus for occluding atypical septal defects.

Bengmark (US Patent 5,152,770) discloses an implantable device for occluding a vessel in a human body.

Wolf (US Patent 4,983,177) discloses an apparatus for occluding body lumens in a reversible manner.

Wright (US Patent 4,946,463) discloses a vessel occluder for cardiac surgery.

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to ARUNDIPTA SHOME whose telephone number is (571)270-5539. The examiner can normally be reached on Monday through Friday 8:30am to 6pm EST.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Justine Yu can be reached on 571-272-4835. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Arun Shome/
Examiner, Art Unit 3771
Oct. 27, 2008

/Justine R Yu/
Supervisory Patent Examiner, Art Unit 3771